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Title: Effectiveness of centre-based childcare interventions in increasing child physical activity: a systematic review and meta-analysis for policy makers and practitioners

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Systematic review; intervention; pragmatic; childcare; physical activity.

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Conflict of Interest:
The authors declare that they have no conflict of interests.
Abstract

Context: The review describes the effectiveness of physical activity interventions implemented in centre-based childcare services and: i) examines characteristics of interventions that may influence intervention effects; ii) describe the effects of pragmatic interventions and non-pragmatic interventions; iii) assesses adverse effects; iv) describe cost effectiveness of interventions

Methods: Data sources were Cochrane Central Register of Controlled trials, MEDLINE, EMBASE, PsycINFO, ERIC, CINAHL, SCOPUS, SPORTDISCUS. Studies selected included randomized controlled trials conducted in centre-based childcare including an intervention to increase objectively measured physical activity in children aged less than six years. Data were converted into standardized mean difference and analysed using a random effects model.

Results: Overall interventions significantly improved child physical activity (SMD =0.44; 95% CI:0.12-0.76). Significant effects were found for interventions that included structured activity (SMD 0.53; 95% CI: 0.12-0.94), delivery by experts (SMD 1.26, 95% CI: 0.20-2.32) and used theory (SMD 0.76, 95% CI: 0.08- 1.44). Non-pragmatic (SMD 0.80, 95% CI:0.12-1.48) but not pragmatic interventions (SMD 0.10, 95% CI:-0.13-0.33) improved child physical activity. One trial reported adverse events and no trials reported cost data.

Conclusions:

Intervention effectiveness varied according to intervention and trial design characteristics. Pragmatic trials were not effective and information on cost and adverse effects was lacking. Evidence gaps remain for policymakers and practitioners regarding the effectiveness and feasibility of childcare-based physical activity interventions.
Introduction

Participation in adequate physical activity is associated with lower prevalence of overweight and obesity in preschool age children and may contribute to sustaining a healthy body weight in later childhood. A number of cross sectional studies conducted with preschool age children have reported positive associations between child participation in physical activity and lower levels of body fat and Body Mass Index (BMI) [1-5]. Longitudinal studies have also found that participation in adequate physical activity in preschool age can protect against development of overweight and obesity in later childhood [1,6-7].

Guidelines internationally, including those in Australia and the United Kingdom, recommend a minimum of three hours of physical activity across the day [8, 9]. In the United States (US) guideline recommendations suggest that preschool age children should engage in two hours of physical activity per day with 60 minutes being structured and at least 60 minutes unstructured. [10]. Despite such guidelines, a systematic review of 39 studies from seven countries found that only 54 percent of children aged two to six years engaged in 60 minutes of MVPA each day[11].

Centre-based childcare (including pre-school early education programs, infant classes, reception classes, nurseries, and day care centres) [12] represents an opportune setting in which to deliver public health interventions to increase young children’s physical activity [13]. In high income countries, childcare services provide access to a significant proportion of the population aged less than five years, often for prolonged periods. In two thirds of all Organization for Economic Cooperation and Development (OECD) countries, 70% of children aged three to five years are enrolled in formal childcare or pre-school programs [14]. In Australia 95% of children attend either
a full-day pre-school or long day care services in the year before commencing formal schooling [15]. As such, effective physical activity interventions delivered in this setting have the potential to positively impact on the health of large numbers of children [16, 17].

Research indicates that young children are not sufficiently active during attendance at childcare [18-21]. To address this, evidence-based initiatives to improve physical activity among children in childcare are required [22]. Research evidence synthesised in systematic reviews and meta-analyses are recognised as important tools for informing policy decisions to improve community health and well-being [23]. Despite their potential to influence policy and practice, systematic reviews often fail to report information needed by policy makers and practitioners to guide such decisions [24]. For example, systematic reviews rarely report effects of health interventions of various intensities, delivered by differing intervention personnel, or using various intervention delivery modalities [25, 26]. Furthermore policy makers are interested in the cost of program delivery, and need to weigh the potential benefits of an intervention against any potential for harm [27], yet less than 15% of systematic reviews of child obesity prevention interventions report cost or adverse event outcomes [28].

Compared with the findings of interventions delivered under tightly controlled research conditions (‘explanatory’ or ‘efficacy’ trials), the impact of an intervention delivered under ‘real world’ conditions (‘pragmatic’ trials) are likely to be of particular interest to policy makers and practitioners as they are more likely to provide a better approximation of the effect of intervention when delivered on a routine basis in the absence of research support and expertise [29]. However,
systematic reviews typically combine both ‘pragmatic’ and ‘explanatory’ trials when synthesising trial effects. As the effectiveness of explanatory interventions may be greater than pragmatic interventions [25, 30, 31], pooling of data may over-estimate the likely impact of interventions when they were delivered in the ‘real world’ [30]. Isolating the effectiveness of pragmatic trials in systematic reviews has the potential to improve the relevance and utility of systematic reviews for practitioners and policy makers [25].

To our knowledge, no previous systematic reviews of childcare-based physical activity interventions have included an examination of the impact of interventions according to their intervention or trial design characteristics, or examined intervention costs and adverse effects. To address this evidence gap, a systematic review of randomized controlled trials of interventions to increase child physical activity delivered in centre-based childcare was conducted. The broad aim of the review was to assess the effectiveness of interventions to improve physical activity among children aged zero to six years attending childcare. Specifically, we sought to examine in trials of physical activity interventions undertaken in centre-based childcare services:

i) the extent to which intervention characteristics influence intervention effects on child physical activity

ii) the effects of pragmatic interventions (as opposed to non-pragmatic) on child physical activity

iii) any unintended adverse effects on childcare services, services staff or children

iv) cost or cost effectiveness
Methods

For the purpose of this review, the term “centre-based childcare” refers to public or private operated facilities that are provided outside the home in licensed centres attended by children aged zero to six years before commencing formal schooling. Services can be full or part time and are commonly referred to as childcare (including pre-school early education programs, infant classes, reception classes, nurseries, and day care centres) [14]. “Physical activity” was defined as any bodily movement produced by skeletal muscles that requires greater energy expenditure than resting which is distinct from the definitions and terms of physical fitness and exercise [32]. This review has been registered with PROSPERO (CRD42015019096) and reported in accordance with PRISMA guidelines [33].

Inclusion criteria

To be included in this review, trials must have fulfilled the following criteria:
(a) include children aged under six years with no diagnosed diseases or health problems; (b) assess the effects of interventions carried out in centre-based childcare with at least one component/strategy aimed at increasing the physical activity level of attending children (including educational, experiential, health promotion and/or structural or environmental interventions); (c) use an objective measure to assess physical activity (including pedometer or accelerometer); (d) employ a randomized study design (including cluster-randomized controlled trials); (f) be published in a peer reviewed journal in English. No limit was set on date of publication. See Appendix 1 for detailed search terms.
Search methods
A computer based literature search was carried out on 10th -12th September 2014. The search was conducted in the following electronic data-bases: the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library, MEDLINE (1946 to 2014), EMBASE (1947 to 2014), PsycINFO (1950 to 2014), ERIC (up to 2014), and CINAHL (up to 2014), SCOPUS (up to 2014), SPORTDISCUS (up to 2014). The Medline search strategy included filters used in other published systematic reviews for ‘physical activity’ [34], ‘population’ (childcare services) [35] and ‘interventions’ [36]. Reference lists of previous reviews were searched by MF for potential studies missed in the initial literature searches. Author MF screened abstracts and titles. Full texts manuscripts obtained for potentially eligible trials were independently assessed for eligibility by authors MF and JJ against the inclusion criteria. In instances where the eligibility of studies was not resolved via consensus, a decision was made by a third reviewer (LW).

Data Extraction
Trial data were extracted using a standardized data-extraction form based on the Cochrane Public Health Group Methods Manual [37], which was piloted prior to initiation of the review. Authors MF and JJ, not blind to author or journal information, independently extracted the data. Multiple attempts were made to contact authors to source relevant data when it was not available in the publication. Discrepancies between reviewers in data extraction were resolved by consensus or if required via a third reviewer (LW). Where available, the following information was extracted:

- *Descriptive information:* authors; year of publication; country; target population; setting; number of participants; participants' age; gender, ethnicity, and socioeconomic or geographical status.
Information on other intervention characteristics: Intervention strategies/components, duration, delivery personnel, and theoretical basis for the intervention.

Information to enable intervention classification as pragmatic (or non-pragmatic). Trials were assessed and scored using the pragmatic-explanatory continuum indicator summary tool (PRECIS-2) [32]. The PRECIS-2 tool was developed by a group of international researchers and methodologists and has been previously applied in a number of systematic reviews [25, 30, 38, 39]. Each trial was scored across nine domains using a five-point likert scale (1: very explanatory, 2: rather explanatory, 3: equally pragmatic and explanatory, 4: rather pragmatic, 5: very pragmatic). Scoring was completed according to definitions and criteria set by the tool developers (Table 1)[40].

Information on the trial physical activity outcome measure: Assessment method, assessment periods, and length of follow up. Measures of physical activity could include pedometer steps or step rates, accelerometer counts or count rates, minutes of moderate to vigorous physical activity (MVPA), time in MVPA or percent time in MVPA.

Information on adverse events: Adverse event outcomes including any reported unintended adverse consequences of an intervention such as any physical, behavioural, psychological or financial impact on the child, parent or family, or to the service or facility where an intervention may have been implemented.

Information on intervention costs: Cost outcomes included any estimates of absolute costs or any assessment of the cost effectiveness of included interventions.

Trial descriptive and outcome data were transcribed and included in study tables by Author MF.
Assessment of risk of bias

The Cochrane Collaboration’s standardized risk of bias tool was used to assess risk of bias [41]. Authors MF and JJ, not blind to author or journal information, independently reviewed and recorded information for all but one of the included studies across the seven specific risk of bias domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and ‘other’ issues. Assessment of risk of bias for the trial conducted by Authors MF, LW, JW and JJ, [42], was undertaken by an independent assessor who had had no involvement in that study. Authors independently assigned a judgment of either ‘low risk’, ‘high risk, or as ‘unclear risk’ of bias for each domain. The assessment process and tools were piloted prior to initiation of the review. Discrepancies between reviewers were resolved by consensus or if required via a third reviewer (LW). Summary figures were generated with the Review Manager software [43].

Data synthesis and analysis

The characteristics of included studies were described narratively. Meta-analysis was performed using a random effects model in Review Manager, version 5.3.5 [43] and reported as a standardized mean difference (SMD) given differences in outcomes and measures reported in included studies [41]. Where multiple measures of physical activity were reported in trials, counts or count rates were used in pooled analyses in preference to measures of MVPA. Measures of physical activity across the day were used in preference to physical activity occurring only in the childcare service. Measures of physical activity occurring at the furthest period from baseline were used in preference to measure of activity occurring during intervention implementation or immediately post
intervention; and data from intention-to-treat trial analyses were used in preference to data included in less conservative analyses. For cluster-randomized trials, the trials’ effective sample size was calculated using the methods described in the Cochrane handbook [41] before pooling with data from individual randomized controlled trials. We used the intra-cluster correlation coefficient (ICC) derived from the trial (if available), otherwise we used an ICC of 0.05 as it represented the median ICC of included trials.

Intervention characteristics identified from previous narrative reviews to be important to intervention effects, or to be of particular relevance for policy makers and practitioners [26, 36, 44, 45], were investigated. These analyses were performed for interventions that included the following components (in isolation or in conjunction with others): structured lessons which included planned teacher led activities or programs (yes/no); enhancement of the childcare physical environment (such as provision of equipment, re-arrangement of built environment or addition of playground markings) (yes/no); parent engagement strategies including communication or education (workshop or educational materials) (yes/no). To assess the impact of intervention duration, interventions were grouped into two categories including those of less than six months duration and those greater than six months; To assess the impact of different intervention delivery personnel, subgroups analysis were performed in terms of interventions delivered by: existing teaching or service staff; or by external staff and or experts. For use of theory, trial results were pooled according to an explicit use of a theory or theoretical framework in the design of the intervention (yes/no).
To describe the effects of pragmatic and non-pragmatic interventions, trials were classified as pragmatic or non-pragmatic using the average score across the nine-domains of the PRECIS-2 tool as per the method applied by Koppenaal et al.[39]. Where insufficient data existed to score for such domains, this was scored as missing. Where this occurred the average was calculated without the ‘‘missing value’’. As no cut-off scores are currently provided for the PRECIS-2 tool the scoring method for categorising trials was based on previous studies [30]. Trials were classified as pragmatic if average score was more than 3.3 or greater and non-pragmatic if <3.3.

Where information on adverse events and cost-effectiveness was available, findings of included studies were described narratively.

Visual inspection of funnel plots was undertaken to identify the potential for publication bias. We performed sensitivity analysis removing outliers from pooled analyses based on the inspection of the funnel plots. Statistical heterogeneity was reported using the $I^2$ statistic and explored through sub-group analysis.

**Results:**

After duplicates were excluded a total of 6,132 publications were retrieved from the database searches. After screening the titles and abstracts of the publications, 64 publications were considered potentially eligible. Based on full text review, 47 publications were excluded leaving 17 publications describing 17 unique intervention trials that were included in the review. Primary reasons studies were not included in the review are included in Figure 1[33].
Characteristics of studies included in review

Table 3 shows a summary of the characteristics of the included trials. The trials were published between 2006 and 2014 with seven conducted in the US [46-52], two conducted in Australia [42, 53], Switzerland [54, 55], and Belgium [56, 57], and one each in Germany [58], Israel [59], England [60] and Scotland [61]. Of the 17 trials, six were conducted in areas of low income or social disadvantage [47-51, 60], with four of these conducted with minority populations (African American, Latino and Migrants) [49-51, 55]. The number of services participating in each trial ranged from one to 40, with the number of child participants ranging from 33 to 826. Across the interventions, the mean age range of child participants was between 3.3 and 5.5 years.

Intervention duration across the included trials ranged from two days in one trial [50] to 12 months in another [55]. In five trials intervention duration was between four to eight weeks [46, 51, 52, 60, 62] and between three to five months in six [42, 47, 48, 53, 57, 59]. In a further four, intervention duration was between six to nine months [49, 54, 58, 61].

Structured active lessons were included as an intervention strategy in 13 of the 17 trials [42, 46-49, 51-53, 57, 58, 60, 61]. Other intervention strategies that were either included as a single component or as an additional component to a structured activity intervention included rearrangement of play spaces (n=4) [42, 54, 55, 57], addition of physical activity promoting play equipment/markings (n=2) [53, 56] and teacher engagement/role modelling with children during free play (n=2) [42, 53]. One trial involved scheduling additional outdoor play time [50]. Six of the trials also included a parent component along with service based strategies [46, 47, 55, 57, 58, 61] all of which were information/education focused (newsletters, information sheets or workshops).
with one also including a parent homework strategy. Of the interventions, nine included at least two intervention components [42, 47, 51, 53-55, 57, 58, 61].

Specific intervention theories were specified in seven trials, the socio-ecological model for three [42, 54, 60], social cognitive theory in two [47, 51] and general systems theory [58], and the PRECEDE-PROCEDE model [57] in a single trial each. Childcare staff delivered the intervention in most of the trials (n=11). In two trials the intervention was delivered by research staff or experts [52, 58] and in two, intervention delivery occurred through a combination of research/experts and childcare staff [59, 60].

Physical activity was measured using accelerometers in 14 trials, with the remaining three using pedometers [42, 48, 59]. Outcome data were collected: while intervention support from the research team was still active in four trials [46, 49, 50, 52]; immediately post intervention support in 11 trials [42, 47, 48, 51, 53, 55, 56, 58-61]; and between 1-6 months post intervention support in two trials [54, 57]. In three trials follow-up assessments were carried out at two time points [53, 58, 60].

Based on classification using the PRECIS-2 tool, eight interventions were classified as pragmatic [42, 50, 51, 54, 57, 58, 61] and nine as non-pragmatic [47-49, 52, 53, 55, 59, 60, 62].

**Risk of bias**

Figure 2 shows the results of the risk of bias assessments. It was unclear whether random sequence generation was adequately performed in eight trials due to lack of information in the publication [46-51, 59, 62]. Risk of bias for concealment of allocation sequence was unclear in five trials [47,
Six trials reporting intervention delivery involving research personnel that were not blinded were assessed as high risk of performance bias [42, 47, 49, 50, 52, 59] and in six trials risk was unclear due to lack of information [46, 48, 53, 55, 57, 60]. In regard to detection bias, while only two trials reported blinding of outcome assessors [53, 61] given the objective nature of the measures used, outcomes were judged not likely to be influenced and assessed as low risk. In five trials insufficient information was available regarding numbers and reasons for drop out at follow-up to determine risk of attrition bias [46, 51, 52, 56, 59]. Only three trials provided information to permit judgment of risk for selective reporting [42, 47, 58]. Other potential risks of bias were identified for three trials. Of these, three trials did not adjust their analyses to take account of the effects of clustering in their analysis [48, 51, 59].

**Intervention effects**

Overall, 16 of the 17 included trials provided data to enable inclusion in a meta-analysis. In the remaining study, no numerical data were provided, with the results being presented in visual graphed format only [46]. This study reported significant intervention impact on classroom levels of MVPA relative to the control group at the completion of an eight week intervention involving 10 minute structured active lessons, several times/week.

Figure 3 presents the findings of the meta-analysis for all 16 included studies. Results show a significant effect of interventions (SMD 0.44; 95% CI: 0.12-0.76; p=0.007). In the sensitivity analysis excluding an outlier [55], pooled effect estimates were no longer significant (SMD 0.28; CI: -0.01-0.56; p=0.06). Table 2 presents the findings of the subgroup analysis for intervention characteristics. Interventions that included structured activity lessons showed a significant
intervention effect (SMD 0.53; 95% CI: 0.12-0.94; p=0.01,) as did those not including this strategy (SMD 0.17; 95% CI: -0.01-0.33; p=0.04). A significant effect was observed for interventions with (SMD 0.41; 95% CI: 0.02-0.80; p=0.04) and without an environmental enhancement strategy (SMD 0.73; 95% CI: 0.14-1.32; p=0.02). Interventions that did not include a parent strategy showed a significant effect (SMD 0.54; 95% CI: 0.09-1.00; p=0.02) as did those six months or less in duration (SMD 0.58; 95% CI: 0.10-1.05; p=0.02), where interventions involved delivery by experts (SMD 1.26; 95% CI: 0.20-2.32; p=0.02) and were based on a theory or framework (SMD 0.76; 95% CI: 0.08-1.44; p=0.03).

Figures 4 and 5 present the pooled analysis results for trials classified as pragmatic and non-pragmatic respectively. Pragmatic interventions did not significantly improve child activity (SMD 0.10; 95% CI: -0.13-0.33; p=0.40,) while non-pragmatic interventions showed a significant effect (SMD 0.80; 95% CI: 0.12-1.48; p=0.02).

Cost and adverse events
Of the 17 trials only one reported adverse events and reported no significant difference in the rate of change in injuries per month between intervention and control groups [42]. No trials reported cost data.

Discussion
A comprehensive systematic review of the effectiveness of physical activity interventions in centre-based childcare services was conducted to provide practice relevant information to health policy makers and practitioners. The findings of the review suggest that evidence supporting the
effectiveness of physical activity interventions in this setting are equivocal. A number of intervention characteristics were associated with greater effects including structured activity, use of theory in intervention design and delivery of intervention by experts or external staff. The review did not find evidence to support the effectiveness of pragmatic interventions; however, meta-analysis of non-pragmatic interventions suggests they are effective in improving child physical activity. Despite the importance to policy makers and practitioners of information regarding any associated adverse events of intervention, only one trial reported this information, while no trials reported data on intervention costs or cost effectiveness.

Meta-analysis of 16 of the 17 included trials showed a significant effect favoring interventions (SMD 0.44; 95% CI: 0.12-0.76). Such findings are consistent with those of the only other comparable meta-analysis reporting a significant pooled effect on preschoolers physical activity in a sub-group analysis of physical activity interventions conducted in early childhood education settings [63]. However, funnel plots suggesting the presence of publication bias, and sensitivity analysis that involved removing one outlying trial produced pooled effects that were no-longer significant. Other systematic reviews, which have synthesized trial evidence narratively, have suggested that the effectiveness of physical activity interventions in childcare settings are equivocal [36, 44, 64]. For example, in the review of physical activity interventions delivered in centre-based childcare conducted by Ward, half of the eight studies identified with a physical activity outcome showed non-significant findings [44].

Analyses for intervention characteristics suggest that interventions including structured activity lessons were effective, a finding supported by correlational studies [65-67] and previous reviews [44, 63]. Consistent with a previous systematic review, interventions including enhancements to
the physical environment were found to be effective as were interventions delivered by external experts [45]. Interventions including a parent component were, however, not effective. Intervention strategies targeting parents included in the review primarily involved the distribution of newsletters, information leaflets and education sessions. This finding may therefore suggest that more intensive parent strategies may be required to improve child physical activity behaviours [61, 68]. While data within the childcare setting are limited, parent communication and engagement strategies are an important component of recommended approaches to implementing setting based interventions to promote child health [69] and have been associated with greater intervention effects in school based physical activity interventions [70]. Further research using more direct and engaging strategies may be required to establish the potential value of parents in maximising the effectiveness of physical activity interventions in this setting.

Compared to interventions not utilizing theory in their design, those using theory demonstrated an effect that was significant (SMD: 0.76; 95% CI: 0.08-1.44). While it has long been suggested that the effectiveness of interventions are maximised where an appropriate theoretical framework is utilised to guide intervention development [71], this is the first investigation of its effect for physical activity interventions delivered in the childcare setting. It should be noted however that the 11 studies that did not report on a "theory" may have integrated a theory or conceptual knowledge within their design but not included this information in their paper. As such this finding should be interpreted with caution.
While there was evidence to support the effectiveness of non-pragmatic interventions, pragmatic interventions in this setting did not significantly improve child physical activity. Similar findings have been reported in reviews of other child health interventions [25, 30, 31]. For example a meta-analysis of 49 child obesity prevention interventions found that the overall effect of pragmatic trials on body mass index was non-significant while a significant effect was found in trials that were explanatory in design [30]. Such findings may be a result of difficulties experienced by childcare staff in implementing interventions with high fidelity. For example, the pragmatic intervention conducted by Finch [42] reported that service staff failed to deliver a number of key intervention components [42]. Similarly the pragmatic trial conducted by Bonvin and colleagues reported inadequate dose of structured physical activity and heterogeneous intervention implementation in their evaluation of a large scale government led physical activity program [54]. Findings also suggest that there is a gap in available information required to effectively inform intervention implementation strategies. For example in half of the ten interventions reliant on real-world staff to conduct the intervention limited information was reported on the type and nature of training employed to support implementation. Without such data practitioners are left bereft of key information required to effectively implement such programs. These findings underscore the need for implementation and dissemination research to be prioritised to inform strategies that may be most effective in improving implementation of programs in this setting.

None of the included trials reported cost analyses and only one examined any unintended adverse effects. The trial by Finch and colleagues [42] found no difference in the injury rate of staff or children over the intervention period. The findings of this review suggest that information regarding adverse events is currently not available in trials to inform policy decisions and
highlights the need for future childcare-based physical activity interventions to include these outcomes [28].

Strengths of this review include the use of a comprehensive and rigorous methodology including a broad search strategy, screening of trials, extraction of data, and appraisal of risk of bias using two independent reviewers. In regard to quality of the trials where reporting was sufficient, the overall quality of studies in this review was high. While information to assess reporting bias was insufficient for most studies, overall most were assessed as having a low risk of bias across a number of domains. Despite this, it should be noted that five of the included trials were small pilot studies involving two or less childcare centres. There was also considerable variation within the characteristics of included trials. For all but one analysis, \( I^2 \) statistics indicate considerable heterogeneity (72-97%) and heterogeneity remained high following subgroup analysis. Future systematic reviews, with a greater number of included studies will have greater capacity to examine findings for trials with large sample sizes and explore such heterogeneity. It should also be acknowledged that while we examined the effects of individual components many of the interventions included in our analysis were multi-component, as such we were unable to separate out the contribution of different intervention factors. Future research would benefit from employing factorial designs to isolate effects of specific intervention strategies allowing reviews to examine characteristics of interventions most likely to contribute to positive intervention effects.

Conclusions
Despite aiming to generate practice relevant information, our findings indicate the current evidence base for childcare delivered physical activity interventions provides limited direction for policy makers and practitioners. The results showed that pragmatic interventions are not likely to be effective and that information on cost and adverse effects is almost universally lacking. However positive effect sizes were identified for a number for intervention characteristics, such that structured activity, environmental enhancements and use of theory should continue to be recommended for childcare based interventions broadly.

**Author information**

First author MF led the development of this manuscript. Authors LW, JW and MF, conceived the review. Author LW completed the meta-analysis. All authors contributed to, read and approved the final version of this manuscript.

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43. Review Manager (RevMan), [Computer program]. Version 5.3.5. The Nordic Cochrane Centre: Copenhagen 2014.


69. International Union for Health Promotion and Education. *Achieving health Promoting schools: Guidelines for promoting Health in schools.*


Records identified through database searching (n = 7825)
Additional articles identified through reference list search (n = 2)

Records after duplicates removed (n = 6132)

Records screened (n = 6132)

Records excluded (n = 6069)

Full-text articles excluded (47)
n= 9 article not a primary study (abstract, commentary, reviews, protocol),
n=5 did not report on an intervention
n=5 utilized a non-randomised study design
n=6, did not assess physical activity using an objective measure
n=11 did not include physical activity as an outcome
n=2 the entire population of children in the study overweight
n=2 the evaluation did not report physical activity outcomes for the comparison group
n=7 the intervention was not delivered in a childcare setting

Full-text articles assessed for eligibility (n = 64)

Studies included in qualitative synthesis (n = 17)

Excluded from Meta-analysis
n = 1 data presented as graphed figures, author did not respond to request for numerical data

Studies included in overall quantitative synthesis (meta-analysis) (n = 16)
Figure 2: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.
**Figure 3. Standardised mean difference in objectively measured physical activity across all interventions**

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<td>Ellis 2007</td>
<td>6.9 (76.2)</td>
<td>5.4 (6.9)</td>
<td>4.32 (0.00, 0.45)</td>
</tr>
<tr>
<td>Finch 2014</td>
<td>15.0 (6.7)</td>
<td>13.8 (6.6)</td>
<td>0.34 (0.11, 0.00)</td>
</tr>
<tr>
<td>Fitch 2011</td>
<td>67.2 (11.4)</td>
<td>69.4 (11.6)</td>
<td>0.20 (0.34, 0.32)</td>
</tr>
<tr>
<td>Jones 2011</td>
<td>75.0 (11.4)</td>
<td>64.0 (11.5)</td>
<td>0.32 (0.04, 0.04)</td>
</tr>
<tr>
<td>O’Dwyer 2013</td>
<td>58.8 (15.5)</td>
<td>33.8 (13.5)</td>
<td>0.12 (0.32, 0.52)</td>
</tr>
<tr>
<td>Puder 2011</td>
<td>18.8 (19.8)</td>
<td>8.2 (21.5)</td>
<td>0.01 (0.02, 0.19)</td>
</tr>
<tr>
<td>Reilly 2006</td>
<td>80.9 (17.9)</td>
<td>59.9 (21.8)</td>
<td>0.45 (0.01, 0.02)</td>
</tr>
</tbody>
</table>

Total (95% CI) 1363 1281 100.0% 0.44 (0.12, 0.76)

Heterogeneity: Tau² = 0.37, Ch² = 219.07, df = 15 (P = 0.00001), P = 93%
Test for overall effect Z = 2.59 (P = 0.007)

**Figure 4: Standardised mean difference in objectively measured physical activity for pragmatic interventions**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Std. Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Alihassan 2007</td>
<td>56.2 (74.6)</td>
<td>48.2 (114.5)</td>
<td>0.10 (0.99, 0.20)</td>
</tr>
<tr>
<td>Alihassan 2013</td>
<td>9.2 (2.7)</td>
<td>8.8 (2.9)</td>
<td>0.12 (0.39, 0.04)</td>
</tr>
<tr>
<td>Alihassan 2012</td>
<td>7.0 (3.9)</td>
<td>8.9 (3.2)</td>
<td>0.10 (0.28, 0.17)</td>
</tr>
<tr>
<td>Amsel 2012</td>
<td>33.0 (5.3)</td>
<td>28.8 (5.4)</td>
<td>0.41 (0.12, 0.07)</td>
</tr>
<tr>
<td>Bellows 2013</td>
<td>9.2 (5.0)</td>
<td>10.5 (6.1)</td>
<td>0.12 (0.00, 0.36)</td>
</tr>
<tr>
<td>Bowman 2013</td>
<td>76.5 (24.0)</td>
<td>71.1 (21.9)</td>
<td>0.19 (0.01, 0.01)</td>
</tr>
<tr>
<td>Cameron 2009</td>
<td>43.6 (38.6)</td>
<td>58.5 (37.5)</td>
<td>0.13 (0.17, 0.43)</td>
</tr>
<tr>
<td>De Bock 2009</td>
<td>32.9 (18.7)</td>
<td>32.6 (11.9)</td>
<td>0.03 (0.17, 0.23)</td>
</tr>
<tr>
<td>De Graeme 2009</td>
<td>46.6 (9.5)</td>
<td>54.6 (9.9)</td>
<td>0.17 (0.08, 0.04)</td>
</tr>
<tr>
<td>Ellis 2007</td>
<td>6.9 (76.2)</td>
<td>5.4 (6.9)</td>
<td>4.32 (0.00, 0.45)</td>
</tr>
<tr>
<td>Finch 2014</td>
<td>15.0 (6.7)</td>
<td>13.8 (6.6)</td>
<td>0.34 (0.11, 0.00)</td>
</tr>
<tr>
<td>Fitch 2011</td>
<td>67.2 (11.4)</td>
<td>69.4 (11.6)</td>
<td>0.20 (0.34, 0.32)</td>
</tr>
<tr>
<td>Jones 2011</td>
<td>75.0 (11.4)</td>
<td>64.0 (11.5)</td>
<td>0.32 (0.04, 0.04)</td>
</tr>
<tr>
<td>O’Dwyer 2013</td>
<td>58.8 (15.5)</td>
<td>33.8 (13.5)</td>
<td>0.12 (0.32, 0.52)</td>
</tr>
<tr>
<td>Puder 2011</td>
<td>18.8 (19.8)</td>
<td>8.2 (21.5)</td>
<td>0.01 (0.02, 0.19)</td>
</tr>
<tr>
<td>Reilly 2006</td>
<td>80.9 (17.9)</td>
<td>59.9 (21.8)</td>
<td>0.45 (0.01, 0.02)</td>
</tr>
</tbody>
</table>

Total (95% CI) 852 788 100.0% 0.10 (0.012, 0.033)

Heterogeneity: Tau² = 0.07, Ch² = 28.22, df = 6 (P = 0.0001), P = 78%
Test for overall effect Z = 1.94 (P = 0.05)
Figure 5: Standardised mean difference in objectively measured physical activity for non-pragmatic interventions

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Std. Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
</tr>
<tr>
<td>Alhassan 2013</td>
<td>9.2</td>
<td>2</td>
<td>27</td>
</tr>
<tr>
<td>Alhassan, 2012</td>
<td>7.9</td>
<td>3.0</td>
<td>20</td>
</tr>
<tr>
<td>Burrowes 2013</td>
<td>6.028</td>
<td>5.031</td>
<td>36</td>
</tr>
<tr>
<td>Candon 2009</td>
<td>631.6</td>
<td>369.7</td>
<td>67</td>
</tr>
<tr>
<td>Ellsken 2007</td>
<td>5.927</td>
<td>3.54</td>
<td>23</td>
</tr>
<tr>
<td>Fitzgerald 2011</td>
<td>57.26</td>
<td>11.4</td>
<td>65</td>
</tr>
<tr>
<td>Jones 2011</td>
<td>753</td>
<td>299.7</td>
<td>15</td>
</tr>
<tr>
<td>O'Dwyer 2013</td>
<td>35.8</td>
<td>15.5</td>
<td>46</td>
</tr>
<tr>
<td>Puder 2011</td>
<td>817</td>
<td>186</td>
<td>187</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>515</td>
<td>493</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 1.00, Chi² = 181.32, df = 8 (P = 0.00001), I² = 95%
Test for overall effect: Z = 2.20 (P = 0.02)
### Appendix 1:

#### Table 1 Detailed search terms

<table>
<thead>
<tr>
<th>Database</th>
<th>Search term</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cochrane</strong></td>
<td>'Exercis*' or &quot;physical* inactive*&quot; or &quot;physical* activit*&quot; or &quot;Movement skill*&quot; or &quot;Motor skill*&quot; or &quot;Motor Activ*&quot; or &quot;physical education&quot; or &quot;physical fitness&quot; or sedentary or &quot;life style&quot; or lifestyle or leisure or sport* or danc* in Title, Abstract, Keywords and &quot;pre school*&quot; or preschool* or childcare or &quot;child care&quot; or daycare or &quot;day care&quot; or &quot;early child*&quot; or nursery or nurseries or kinder* in Title, Abstract, Keywords and &quot;health education&quot; or &quot;health promotion&quot; or policy or policies or promot* or educat* or program* or prevention* or train* or (&quot;physical activity*&quot; w/6 intervention*) or (&quot;physical inactivity*&quot; w/6 intervention*) in Title, Abstract, Keywords</td>
</tr>
<tr>
<td><strong>ERIC</strong></td>
<td>(Random* or “clinical trial*” or placebo* or “research design*” or “intervention stud*” or “evaluation stud*” or “comparative stud*” or “longitudinal stud*” or “cross over stud*” or “latin square” or “time series” or (before near/2 after near/3 (stud* or trial* or design*))) or ((singl* or doubl* or trebl* or tripl*) near/5 (blind* or mask*)) or “matched communities” or “matched schools” or “matched populations” or control* or “comparison group*” or “control group*” or “matched pairs” or “outcome stud*” or quasiexperimental or “quasi experimental” or “pseudo experimental” or nonrandomi* or “non randomi*” or “pseudo randomi*” or “quasi randomi*” or prospective* or volunteer*) AND (Exercis* or “physical* inactiv*” or “physical* activ*” or “Movement skill*” or “Motor skill*” or “Motor Activ*” or “physical education” or “physical fitness” or sedentary or “life style” or lifestyle or leisure or sport* or danc*) AND (“pre school*” or preschool* or childcare or “child care” or daycare or “day care” or “early child*” or nursery or nurseries or kinder*) AND (“health education” or “health promotion” or policy or policies or promot* or educat* or program* or prevention* or train* or (“physical activity*” w/6 intervention*) or (“physical inactivity*” near/6 intervention*)) Separate searches in abstract, title, subject, identifier fields, then de-duplicated</td>
</tr>
<tr>
<td><strong>SCOPUS</strong></td>
<td>ABS TITLE ( ( random* OR &quot;clinical trial*&quot; OR placebo* OR &quot;research design*&quot; OR &quot;intervention stud*&quot; OR &quot;evaluation stud*&quot; OR &quot;comparative stud*&quot; OR &quot;longitudinal stud*&quot; OR &quot;cross over stud*&quot; OR &quot;latin square&quot; OR &quot;time series&quot; OR ( before W/2 after W/3 ( stud* OR trial* OR design* ) ) OR (( singl* OR doubl* OR trebl* OR tripl*) W/5 ( blind* OR mask* )) OR &quot;matched communities&quot; OR &quot;matched schools&quot; OR &quot;matched populations&quot; OR control* OR &quot;control group*&quot; OR &quot;matched pairs&quot; OR &quot;outcome stud*&quot; OR quasiexperimental or “quasi experimental” or “pseudo experimental” or nonrandomi* or “non randomi*” or “pseudo randomi*” or “quasi randomi*” or prospective* or volunteer*) AND (Exercis* or “physical* inactiv*” or “physical* activ*” or “Movement skill*” or “Motor skill*” or “Motor Activ*” or “physical education” or “physical fitness” or sedentary or “life style” or lifestyle or leisure or sport* or danc*) AND (“pre school*” or preschool* or childcare or “child care” or daycare or “day care” or “early child*” or nursery or nurseries or kinder*) AND (“health education” or “health promotion” or policy or policies or promot* or educat* or program* or prevention* or train* or (“physical activity*” w/6 intervention*) or (“physical inactivity*” near/6 intervention*)) Separate searches in abstract, title, subject, identifier fields, then de-duplicated</td>
</tr>
</tbody>
</table>
"comparison group*" OR "control group*" OR "matched pairs" OR "outcome stud*" OR quasiexperimental OR "quasi experimental" OR "pseudo experimental" OR nonrandomi* OR "non randomi*" OR "pseudo randomi*" OR "quasi randomi*" OR prospective* OR volunteer* ) AND ( exercis* OR "physical* inactiv*" OR "physical* activ*" OR "Movement skill*" OR "Motor skill*" OR "Motor Activ*" OR "physical education" OR "physical fitness" OR sedentary OR "life style" OR lifestyle OR leisure OR sport* OR danc* ) AND ( "pre school*" OR preschool* OR childcare OR "child care" OR daycare OR "day care" OR "early child*" OR nursery OR nurseries OR kinder* ) AND ( "health education" OR "health promotion" OR policy OR policies OR promot* OR educat* OR program* OR prevention* OR train* OR ( "physical activity*" W/6 intervention* ) OR ( "physical inactivity*" W/6 intervention* ) )

SPORTDISCUS ( random* OR "clinical trial*" OR placebo* OR "research design*" OR "intervention stud*" OR "evaluation stud*" OR "comparative stud*" OR "longitudinal stud*" OR "cross over stud*" OR "latin square" OR "time series" OR ( before n2 after n3 ( stud* OR trial* OR design* ) ) OR (( singl* OR doubl* OR trebl* OR tripl* ) n5 ( blind* OR mask* ) ) OR "matched communities" OR "matched schools" OR "matched populations" OR control* OR "comparison group*" OR "control group*" OR "matched pairs" OR "outcome stud*" OR quasiexperimental OR "quasi experimental" OR "pseudo experimental" OR nonrandomi* OR "non randomi*" OR "pseudo randomi*" OR "quasi randomi*" OR prospective* OR volunteer* ) AND ( exercis* OR "physical* inactiv*" OR "physical* activ*" OR "Movement skill*" OR "Motor skill*" OR "Motor Activ*" OR "physical education" OR "physical fitness" OR sedentary OR "life style" OR lifestyle OR leisure OR sport* OR danc* ) AND ( "pre school*" OR preschool* OR childcare OR "child care" OR daycare OR "day care" OR "early child*" OR nursery OR nurseries OR kinder* ) AND ( "health education" OR "health promotion" OR policy OR policies OR promot* OR educat* OR program* OR prevention* OR train* OR ( "physical activity*" n6 intervention* ) OR ( "physical inactivity*" n6 intervention* ) )

Separate searches in abstract, title, Keywords, subject heading fields, then de-duplicated